

OPERATIONAL BULLETIN: OBO-2020-038

TITLE: Health Canada Interim Approach for COVID-19 Health Product Imports

Date of Issue: 2020-05-06	Mode(s):	Target Audience: National	Area of Interest: Traveler/ Commercial
	1		Confinencial

Details:

- The purpose of this bulletin is to advise border services officers (BSOs) of Health Canada's priorities regarding health products to be referred to HC in light of the COVID-19 pandemic.
- Due to the unprecedented demand and urgent need for access to health products during the COVID-19 pandemic, Health Canada (HC) is placing priority for inspections on COVID-19 related products, including unlawful claims.
- As a result, nonCOVID-19 related health products only need to be referred to Health Canada as described in the priorities below.
- Products are to be referred to HC based upon the risk they represent, including but not limited to:
 - Highest risk COVID-19 related health products including but not limited to diagnostic test kits, ventilators, sanitizers/disinfectants or any suspect counterfeit/fraudulent health products which include but are not limited to unauthorized COVID-19 Personal Protective Equipment (PPE's) destined to healthcare providers
 - High risk any unauthorized health products including nonCOVID-19 destined to commercial entities for further distribution in Canada, and that require licences or permits at the time of importation e.g. drugs, medical devices, APIs/cutting agents, and products/importers for which import alerts have been issued
 - Low risk up to six months' supply of health products (Over-The-Counter and Natural Health Products) destined to individuals for personal use (reasonable amounts for 180 day supply within a 180 day period), and products including PPE's that appear from original packaging to be for industrial use and not destined for use in healthcare



Actions required by border services officers:

As an **interim measure** due to circumstances surrounding COVID-19, personal shipments of up to 180 days' supply based on direction for use of OTCs, NHPs, and prescription drugs with or without health claims may be imported for personal use.

Examples of recommended referrals:

General

BSOs will detain and refer health products per the priorities listed above to the following to the regional HC Border Office ($\underline{D19-9-1}$ Appendix B – Human Drugs, Natural Health Products and Medical Devices) for an admissibility recommendation by Health Canada. Please note the update email addresses:

BC: hc.bc.border-frontiere.sc@canada.ca

AB: ab.border-frontiere@hc-sc.gc.ca

MB/SK: MB SK.Border-Frontieres@hc-sc.gc.ca

ON: ON.Border-Frontiere@hc-sc.gc.ca QC: hc.qc.border-frontiere.sc@canada.ca ATL:hc.atl.border-frontiere.sc@canada.ca

References

 $\underline{D19-9-1}$ The Administration of Health Canada Acts and Regulations Relating to Certain Controlled, Prohibited or Regulated Goods

Single Window (SW), Integrated Import Declaration (IID), Service Option 911 – Health Canada Personal Protection Equipment (PPE) Entries

Interim Order: Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html



Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19

https://www.canada.ca/en/health-canada/services/drugs-healthproducts/compliance-enforcement/covid19-interim-order-drugs-medical-devicesspecial-foods.html

Contact Information:

Other Government Departments Programs Unit Programs and Policy Management Division Commercial Programs Directorate Commercial and Trade Branch

Any questions regarding this bulletin in the traveler mode should be directed to the regional Corporate and Program Services Divisions, which (if required) will then send an email to the Port of Entry Operations' generic inbox

Any questions regarding this bulletin from field operations in the commercial mode should be submitted to their Commercial Regional Program Officer (RPO). If the RPO requires further assistance, an e-mail can be forwarded to the Commercial Operations generic inbox at

Approved by:

Lidija Lebar, Director Program and Policy Management Division Commercial and Trade Branch

Effective Date: 2020-05-06 Updated: N/A

Additional bulletins:

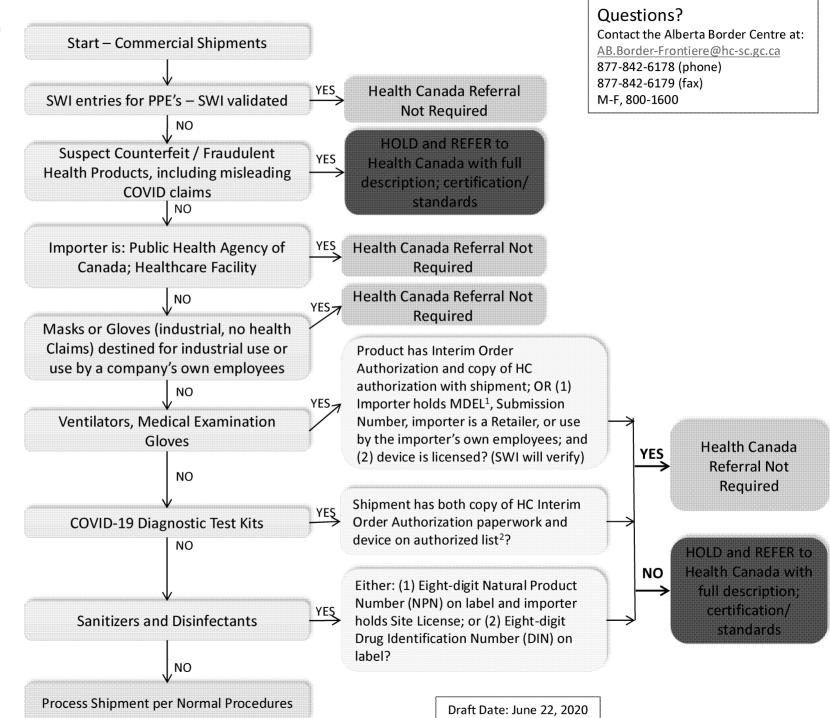


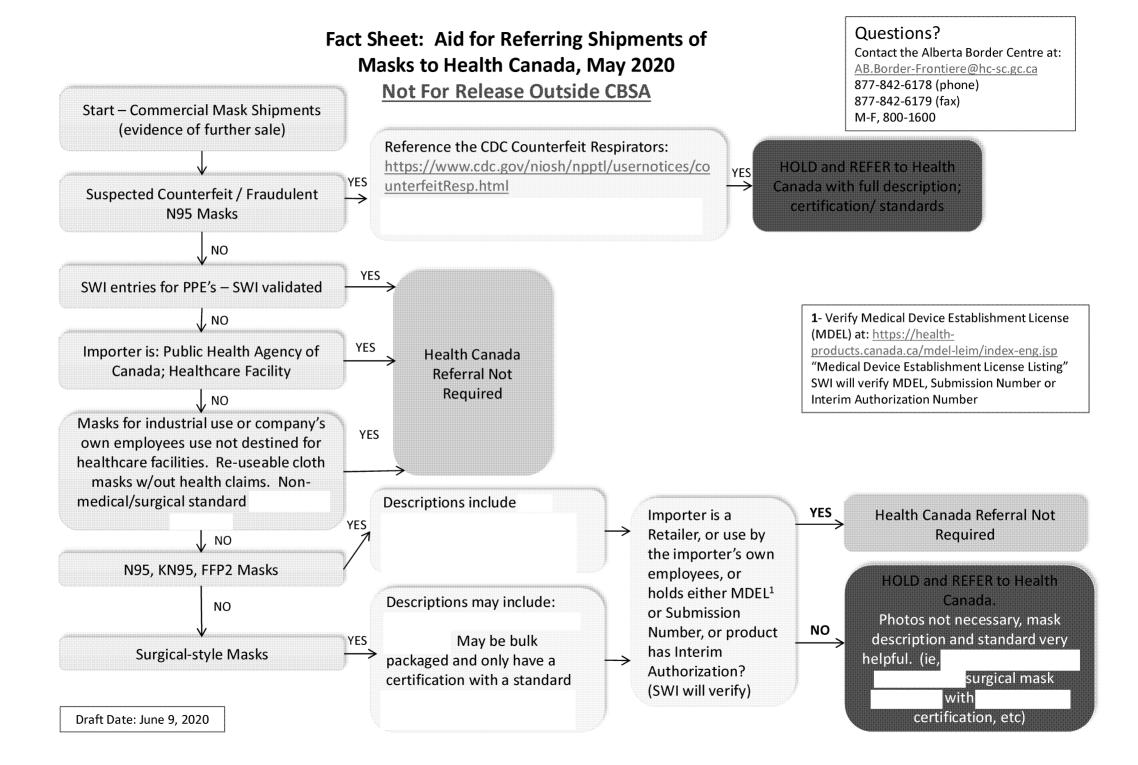
Not For Release Outside CBSA

Start - Personal Shipments As a guide, Masks/person. Gloves/person, and < 180 day supply of Over-The-Counter Drugs and Natural Health Products incl. Disinfectants and Sanitizers /person. Use discretion to determine if for importer's own use: NO Health Canada Follow Referral Not Commercial Required Instructions

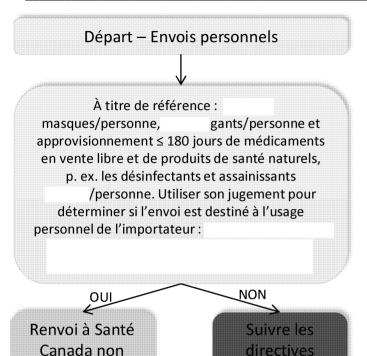
1- Verify Medical Device Establishment Listing (MDEL) at: https://health-products.canada.ca/mdelleim/index-eng.jsp "Medical Device Establishment License Listing" SWI will verify MDEL, Submission Number or Interim Authorization Number

2 – Verify Test Kits at:





Pour usage interne de l'ASFC seulement

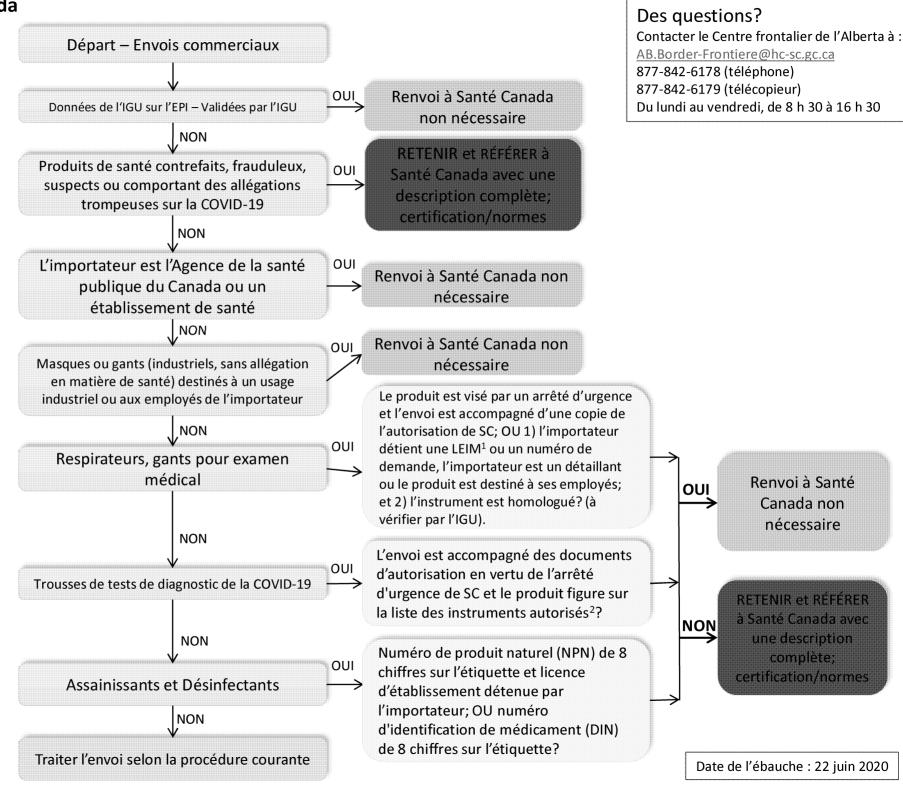


commerciales

1- Vérifier les licences d'établissement d'instruments médicaux (LEIM) à : https://produits-sante.canada.ca/mdel-leim/index-fra.jsp « Des licences d'établissement pour les instruments médicaux » L'IGU vérifiera les LEIM, les numéros de demande et les numéros d'homologation provisoires.

2 – Vérifier les trousses de tests à :

nécessaire



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Commercial

Instructions

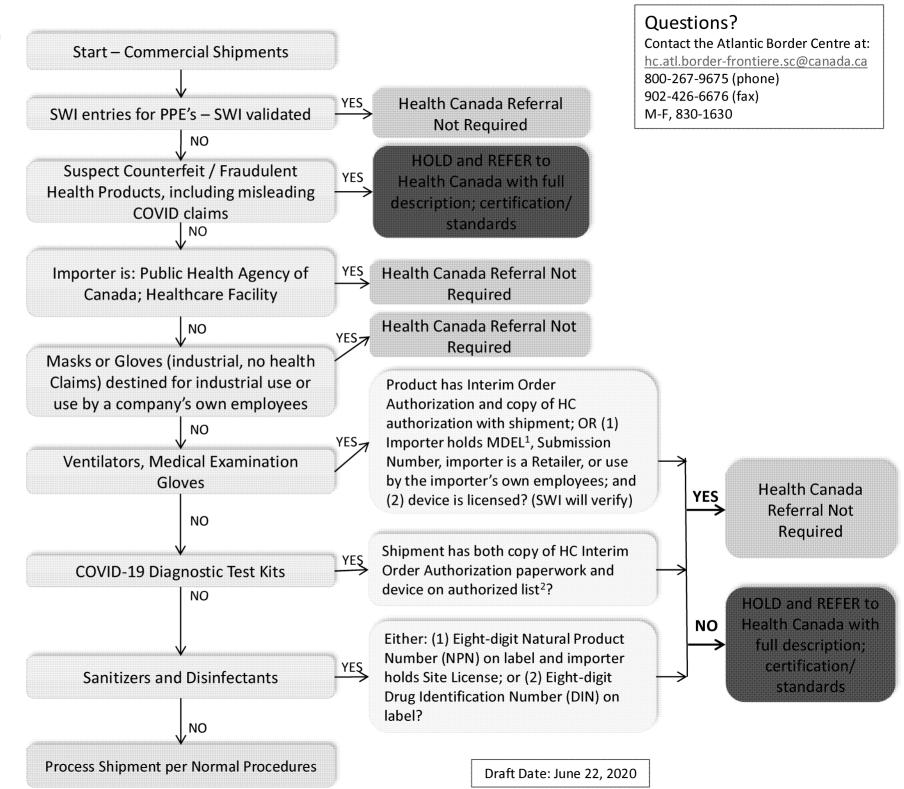
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Health Canada

Referral Not

Required



Canada non

nécessaire

complète;

Fiche d'information : Renvois à Santé Canada concernant la COVID-19, mai 2020

Pour usage interne de l'ASFC seulement

Départ – Envois personnels

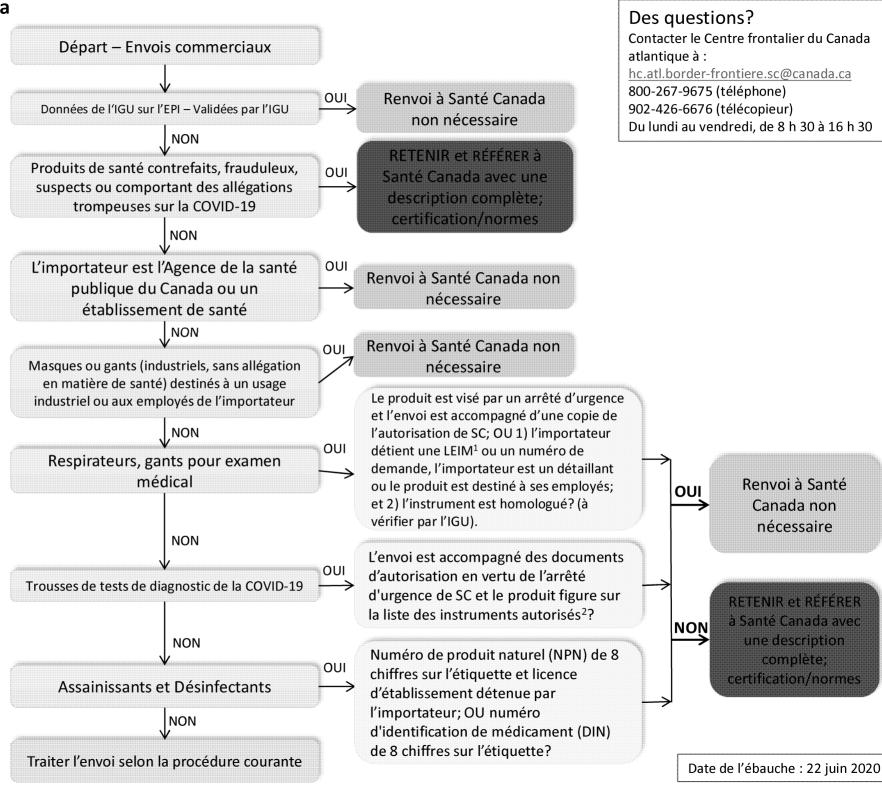
À titre de référence : masques/personne. gants/personne et approvisionnement ≤ 180 jours de médicaments en vente libre et de produits de santé naturels, p. ex. les désinfectants et assainissants

personne. Utiliser son jugement pour déterminer si l'envoi est destiné à l'usage personnel de l'importateur :

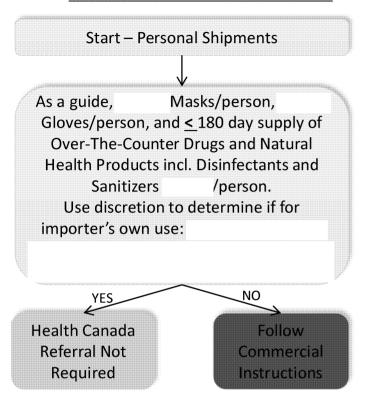
NON Renvoi à Santé Suivre les directives Canada non nécessaire commerciales

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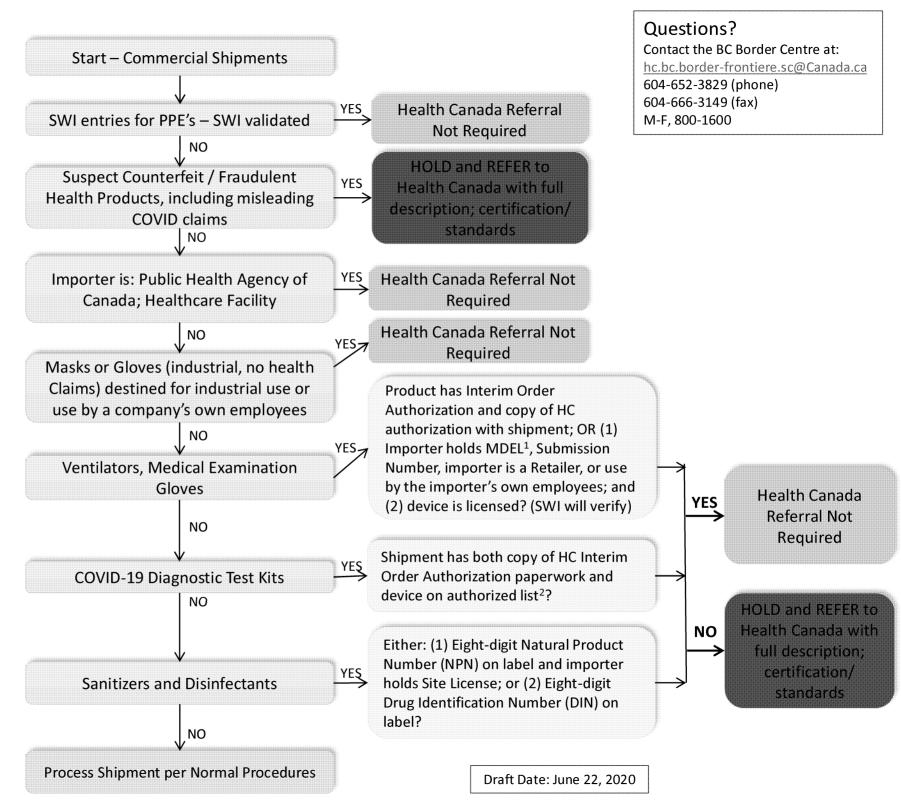


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Renvoi à Santé Canada non nécessaire

personnel de l'importateur :

Suivre les directives commerciales

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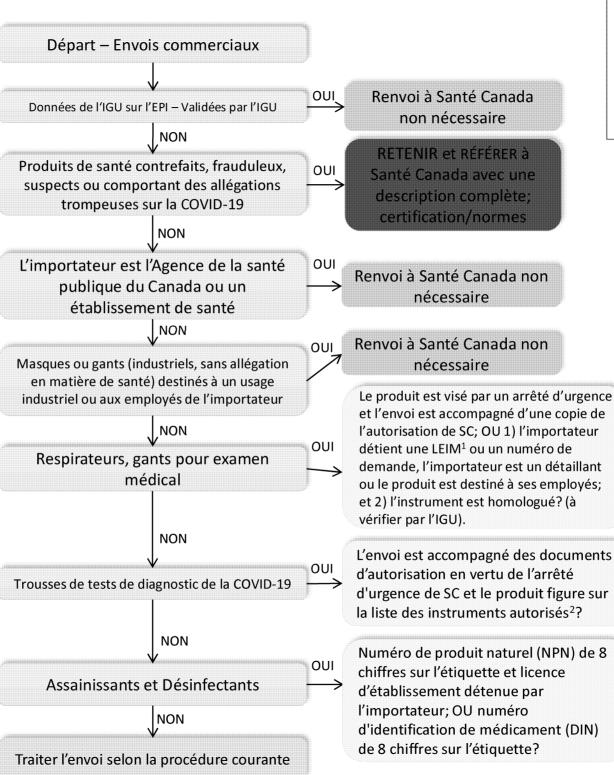
2 – Vérifier les trousses de tests à :

https://www.canada.ca/fr/sante-

canada/services/medicaments-produitssante/instruments-medicaux/covid-19/instruments-

diagnostiques-autorises.html. « Instruments diagnostiques visant une utilisation contre le coronavirus (COVID-19):

Liste d'instruments autorisés »



Des questions?

non nécessaire

RETENIR et RÉFÉRER à

description complète:

certification/normes

nécessaire

nécessaire

Contacter le Centre frontalier de la Colombie-Britannique à :

hc.bc.border-frontiere.sc@Canada.ca

604-652-3829 (téléphone)

604-666-3149 (télécopieur)

Du lundi au vendredi, de 8 h 30 à 16 h 30

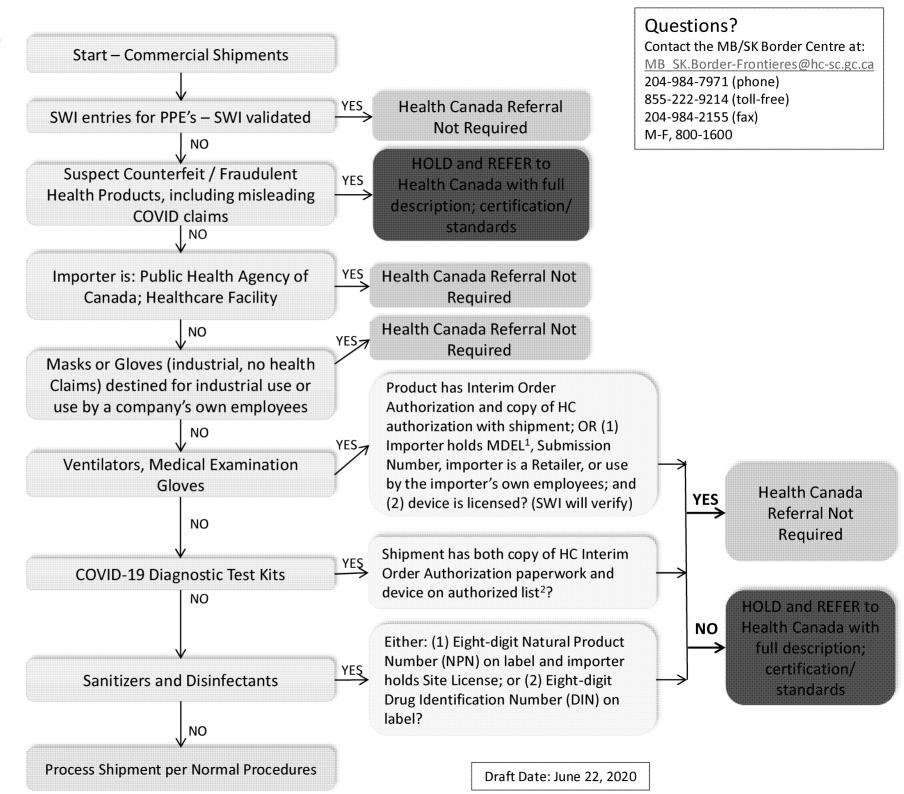
Renvoi à Santé OUI Canada non nécessaire RETENIR et RÉFÉRER à Santé Canada avec NON une description complète; certification/normes Date de l'ébauche : 22 juin 2020

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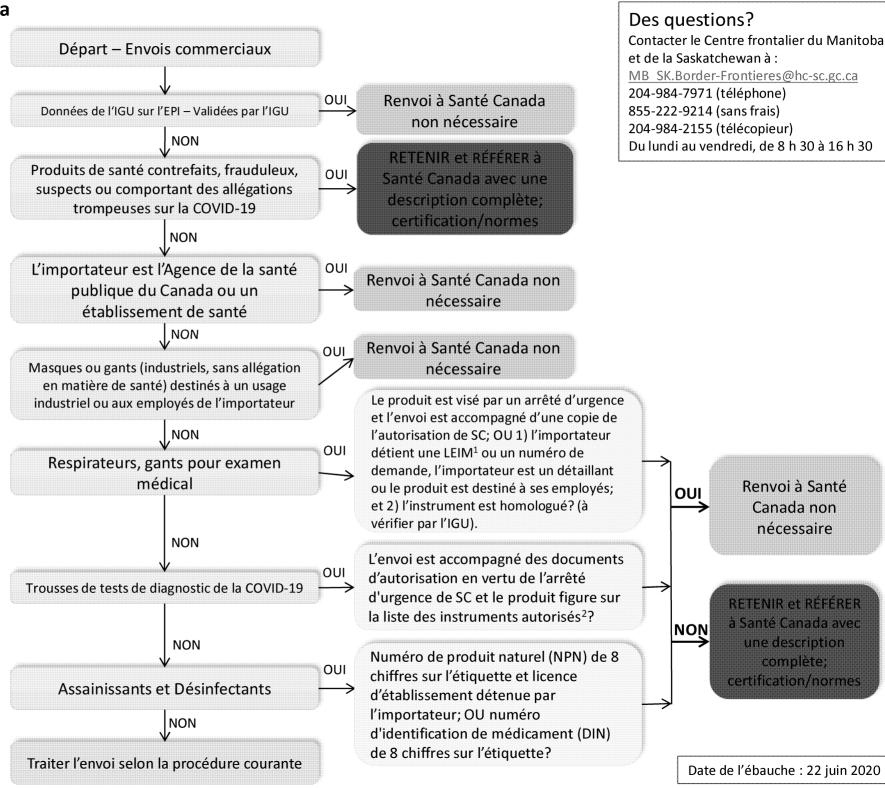
Renvoi à Santé Canada non nécessaire

Suivre les directives commerciales

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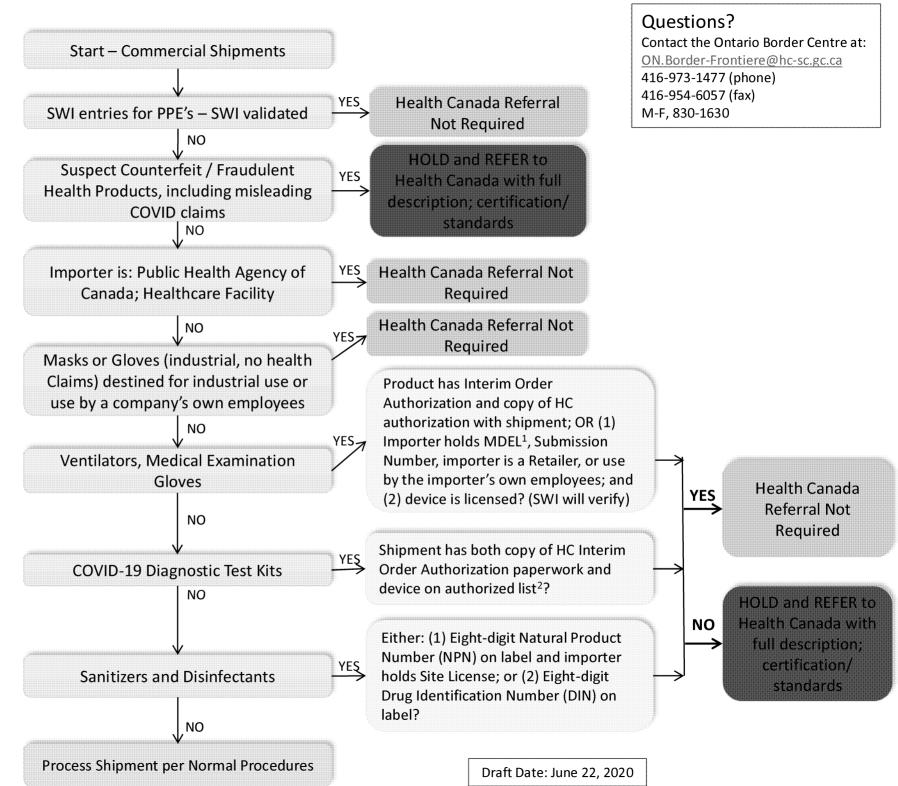
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Referral Not
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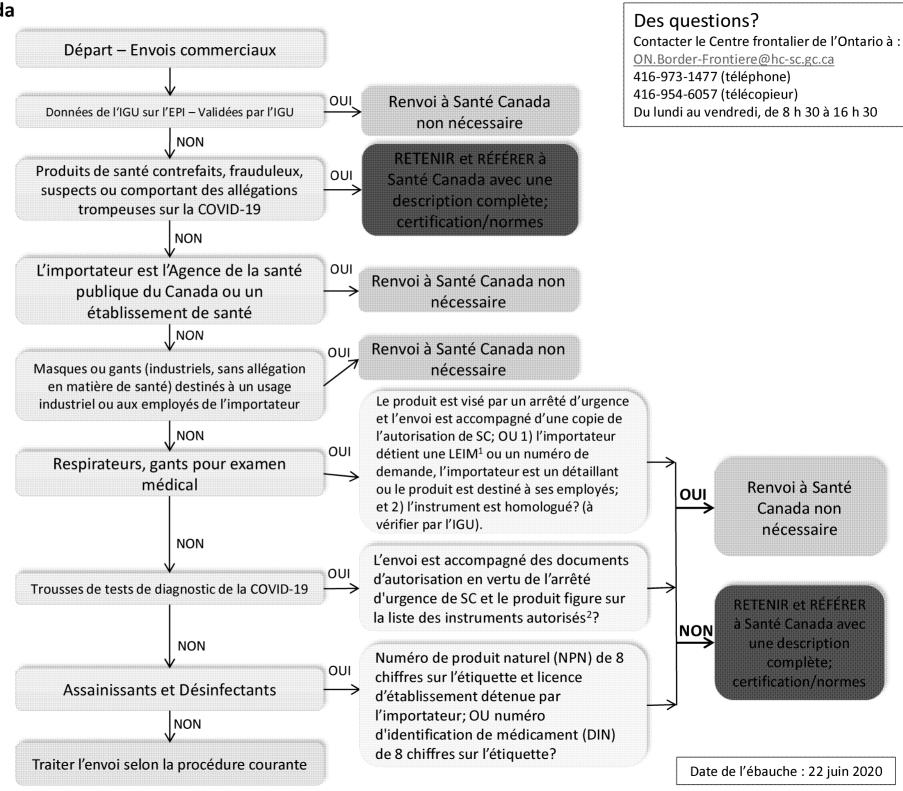
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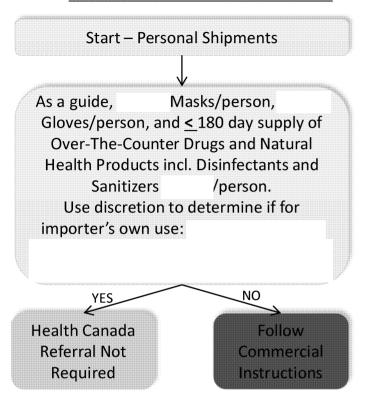
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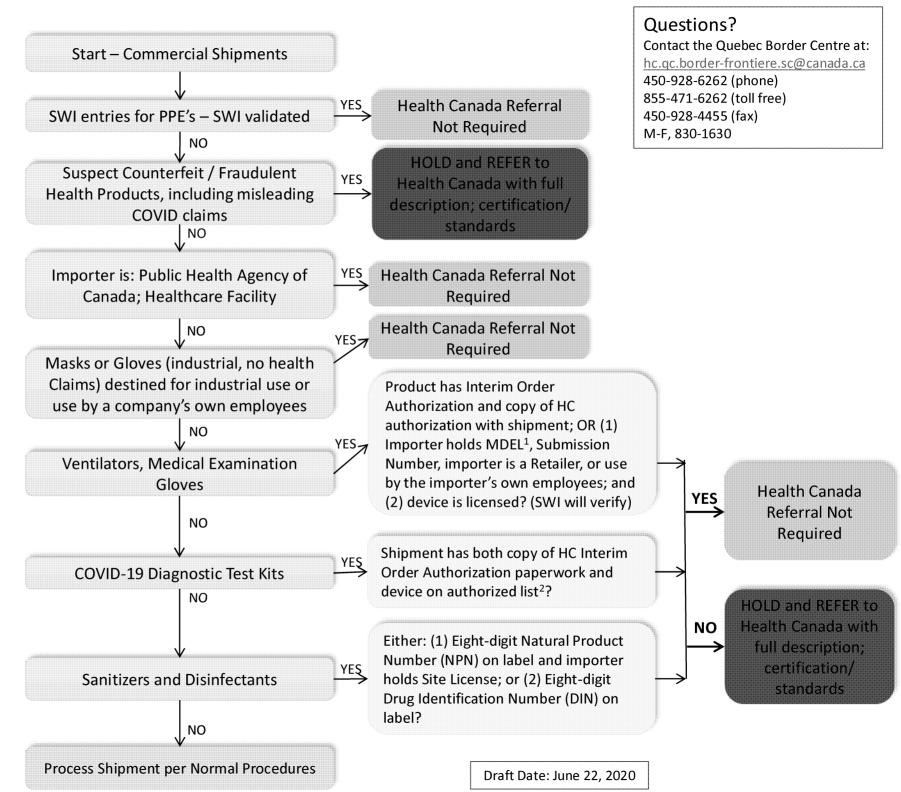


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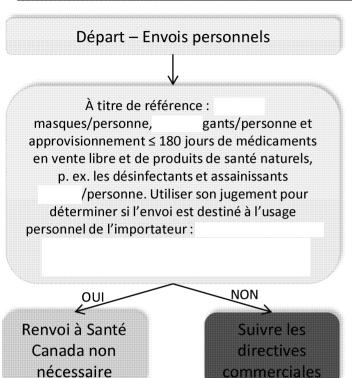


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